

Per Curiam

BENTEN ET AL. v. KESSLER, COMMISSIONER,  
FOOD AND DRUG ADMINISTRATION, ET AL.

ON APPLICATION TO VACATE STAY

No. A-40. Decided July 17, 1992

Respondent federal officials confiscated applicant Bente's supply of RU-486, a drug not approved by the Food and Drug Administration (FDA), at airport customs as she tried to import a single dosage in order to induce a nonsurgical abortion. The District Court entered a preliminary injunction compelling the drug's immediate return to Bente, which the Court of Appeals stayed pending an appeal.

*Held:* The application to vacate the stay is denied. Applicants have failed to demonstrate a substantial likelihood of success on the merits of their claim that Bente is entitled to the drug's return on the ground that the administrative document instructing officials to seize the drug was promulgated without notice-and-comment procedures assertedly required by both the Administrative Procedure Act and FDA regulations. The Court expresses no opinion on the merits of the claim that holding the drug would constitute an undue burden upon Bente's constitutionally protected abortion rights, since that claim was addressed neither by the courts below nor by applicants' filings in this Court.

Application denied.

PER CURIAM.

Petitioner Leona Bente wants to use RU-486, a drug not approved by the Food and Drug Administration (FDA), in order to induce a nonsurgical abortion. She tried to import a single dosage of the drug for that purpose, but respondent federal officials confiscated her supply at airport customs. Petitioners filed suit in the District Court for the Eastern District of New York in order to compel the immediate return of the drug to Bente. The District Court entered a preliminary injunction granting this remedy. Respondents appealed, and the Court of Appeals for the Second Circuit stayed the injunction pending the appeal. Petitioners have filed an application to vacate the Court of Appeals' stay. We deny the application.

STEVENS, J., dissenting

Petitioners contend that Benten is entitled to the return of her RU-486 because an administrative document instructing enforcement officials to seize that drug was promulgated without notice-and-comment procedures assertedly required under both the Administrative Procedure Act and FDA regulations. We conclude that petitioners have failed to demonstrate a substantial likelihood of success on the merits of these claims. JUSTICE STEVENS contends that the Government's holding the drug would constitute an undue burden upon Benten's constitutionally protected abortion rights. See *post* this page and 1086. We express no view on the merits of this assertion. The claim under which JUSTICE STEVENS would grant relief was addressed neither by the District Court nor by the Court of Appeals nor by petitioners' filings in this Court. Accordingly, we conclude that it is not properly before us.

Petitioners' application to vacate the Court of Appeals' July 15, 1992, stay pending respondents' appeal, presented to JUSTICE THOMAS and by him referred to the Court, is denied.

*It is so ordered.*

JUSTICE BLACKMUN dissents and would grant the application to vacate the stay.

JUSTICE STEVENS, dissenting.

Whether an undue burden has been imposed on the exercise of a constitutional right depends on the relative significance of the burden, on the one hand, and the governmental interest at stake, on the other.

In this case, applicant Benten's constitutionally protected interest in liberty has two components—her decision to terminate the pregnancy and her decision concerning the method of doing so. The Government does not assert any interest in, or right to, burden the former decision. The Government does, however, assert an interest in the latter

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by protecting Bente from taking medication under the supervision of her doctor instead of undergoing an invasive surgical procedure. In view of the Government's "personal use exception" policy, expressed in the Federal Drug Administration's February 1, 1989, revision of its Regulatory Procedures Manual,\* the only legitimate governmental interest that is now relevant is the interest in avoiding any "significant health risk" associated with the use of this medication when prescribed by a competent physician. There is no evidence in this record that Bente faces any such risk; indeed, on the specific facts of this case, the Government's purported interest actually supports her position. In all events, I am persuaded that the relevant legitimate federal interest is not sufficient to justify the burdensome consequence of this seizure.

Accordingly, I would grant the application.

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\*The Regulatory Procedures Manual provides in pertinent part as follows:

"In deciding whether to exercise discretion to allow personal shipments of drugs or devices, FDA personnel should consider a more permissive policy in the following situations:

"when the intended use is appropriately identified, such use is not for treatment of a serious condition, and the product is not known to represent a significant health risk." Ch. 9-71-30(C).